

Applicant: Romero
Serial No.: 10/782,245
Filed: February 18, 2004

REMARKS

This Amendment is in response to the Office Action mailed June 20, 2008. This reply is timely filed within the three (3) month time period set forth in the ACTION.

As of the mailing of the current Action, claims 23-25, 27-29, 31-45, 47, 51, 68, and 69 are pending. Applicant presents herein, claim amendments and a response to the current Action. Reconsideration is respectfully requested.

I. Terminal Disclaimer

The current Office Action, on pages 5-6, has set forth a provisional rejection based on nonstatutory obviousness type double patenting over copending application 10/910,787.

Applicant submits herewith a terminal disclaimer along with the disclaimer fee to obviate this rejection. Applicant respectfully requests reconsideration and withdrawal of this rejection.

II. REJECTIONS UNDER 35 USC 103(a)

Claims 23-25, 27-29, 31-45, 47, 51, 68, and 69 have been rejected under 35 USC 103(a) as being unpatentable over Skinner (US Pat No. 6,210,710), in view of Miller (US Pat Application Publication No 2005/0008690) further in view of Cristoferi et al. (US Pat. No. 5,252,339).

Applicant notes that rejections over prior art were made in the current Office Action. As such, in view of MPEP 707.07 that requires the Action to be complete as to all matters, Applicant response presented herein is based on the cited references. Applicant understands the MPEP requirement of completeness that the currently pending claims being allowable upon a showing that the claimed invention is patentable over these cited references.

The subject invention, as now claimed, requires, inter alia:

glucosamine or chondroitin to be released at a controlled rate and a formulation coated onto said inert spheres comprising the components (1) a saccharide, (2) a lubricant, (3) a solution having a stabilizing agent, Glucosamine or chondroitin is present in an amount of about 60% to about 95% by weight; (2) said saccharide is present in an amount of about 1.5% to about 15% by weight; (3) said lubricant is present in an amount of about 0.3% to about 3% by weight; (4) said stabilizing agent is present in an amount of

about 20% to about 80% (currently amended claim 23).

The present invention specifically claims a formulation coated onto inert spheres. Skinner, as cited on page 4 of the current Office Action, discloses a composition that is "beneficial because it provides flexibility in release profiles that are stable and economical for compressed tablets (Skinner, col. 1, lines 48-56).

Thus, the disclosure of Skinner is deficient for failing to teach or suggest the formulation coated onto inert spheres as claimed.

The Office Action further combines the disclosure of Skinner with Miller. However, the disclosure of Miller fails to cure the deficiency of Skinner. Miller is cited merely to teach some of the specific limitations of pending dependent claims (see Office Action, page 5). Miller does not have any teaching or suggestion for a formulation to be layered on inert spheres, as currently claimed. The disclosure of Miller is for multi-phase, multi-compartment capsular delivery. Thus, Skinner in view of Miller, fails to teach or suggest the subject invention as now claimed.

Applicant reminds the Office of the long-standing principle that the chemical arts are highly unpredictable and require a higher standard for obviousness determinations.

Although there is a vast amount of knowledge about general relationships in the chemical arts, chemistry is still largely empirical, and there is often great difficulty in predicting precisely how a given compound will behave. In re Dillon 919 F.2d 688, 710 (Fed Cir., 1990).

As stated above, Skinner teaches beneficial tablet formations and has no disclosure for a composition with a formulation layered onto inert spheres as presently claimed. Combination of the teaching of Skinner with the teaching of Miller does not render the subject invention obvious because, as stated above, chemistry is recognized as being unpredictable and Miller has no teaching or suggestion for the claimed formulation layered on inert spheres.

In view of the failure of the cited references to teach, suggest, or provide any type of motivation to modify, in order to achieve the desired and claimed stability, Applicant asserts a rejection under 35 USC 103(a) cannot be properly applied.

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Applicant respectfully requests reconsideration withdrawal of this rejection.

Applicant notes MPEP 707.07 requires an Office Action to complete as to all matters. Thus, Applicant believes the prior art cited to be a complete assertion of relevant prior art. Applicant further asserts the rejections based upon the prior art of record have been overcome.

Based on the Amendments presented herein, Applicant respectfully asserts the application is patentable over the prior art and is now in condition for allowance. If the Examiner believes there are any additional issues that have not been resolved, the Examiner is invited to call the undersigned representative who is attorney of record in this case.

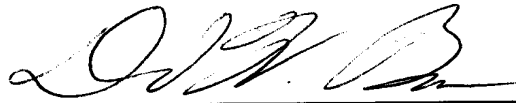
Applicant asserts, no new matter is added by these amendments.

The Commissioner is hereby authorized to charge our Deposit Account No. 19-0734 should any additional fee(s) be required in the filing of this paper to expedite the examination of this application.

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Respectfully submitted,

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